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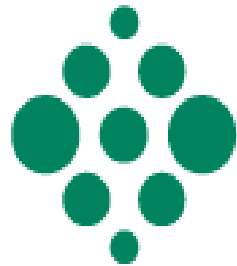


Pharmaceutical Waste Compliance Program



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Corporate Overview



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Stericycle Services

- Medical Waste Management
- Sharps Disposal Management
- Product Recalls & Retrieval
- OSHA Compliance Training
- Pharmaceutical & Medical Device Returns
- Pharmaceutical Waste Compliance
- Healthcare On-site Waste Stream Management
- Medical Safety Product Sales



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Unwanted Medical Disposal

A Common Goal with Different Needs ***“One Size Doesn’t Fit All”***

Hospitals

Retail/Mail-order/Central-fill Pharmacies

Clinics/Physician Practices

Long Term Care Centers

Residential Consumers

- Dispensed to the patient
- Returned (reverse distributor for manufacturer credit or to manufacturer for credit)
- Waste (disposal required)
 - ✓ Clinical/Nursing staff or Pharmacy declares a RX waste
 - ✓ Decision made on Patient floor or in the Pharmacy



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REVERSE DISTRIBUTION RX RETURNS



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RX Reverse Distribution

- **Industry started in early 1990's**
- **Service of convenience**
- **Simplify RX returns process**
- **Maximize manufacturer credits**
- **Regulated by EPA & DOT**
- **Credit value to the medical industry**

Manufacturer Return Good Policies

<u>Policy Variable</u>	<u>Description</u>
Dating (in-date)	From X months before expiration date Upon expiration
Dating (out-dated)	Up to 12 months after expiration date
Quantity (partials)	Partial credits for liquids, tablets, capsules No partial credits for partial vials, ampoules, topicals
Packaging	In original manufacture packaging only
Special Sale	Some products sold as “non-returnable” Specific Lot numbers may be “non-returnable”
Specific Product(s)	Specific products sold as “Non-returnable”



- Must determine if returnable for credit by the manufacturer
- May be returned directly to manufacturer
- May be returned through a reverse distribution company which sets up agreements with the manufacturers and follows through on policies set by the manufacturers
- Returned goods are “products” not waste

Not a RX Waste Management Tool



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RX WASTE DISPOSAL



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RX Waste Disposal Assessment

Blood Saturated
Materials



Red Bags

Sharps



Sharps
Containers

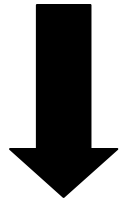
Rx Waste



- **Regulated Medical Waste**
 - Red Bag
 - Sharps Containers
- **Solid Waste**
- **Sewer**
- **Returns shipments through Reverse Distributor**
- **All in one container as hazardous waste**

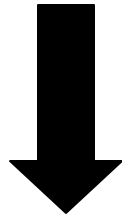
DOT Level Segregation

Non-RCRA



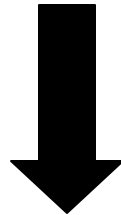
**Non-RCRA
Rx Waste
Container**

Hazardous DOT
Classes 3, 4 & 6



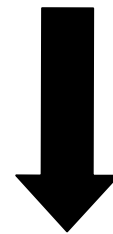
**Hazardous
Flammable &
Toxic/Poisons**

Hazardous DOT
Class 2



**Hazardous
Flammable**

Hazardous DOT
Non-compatible*
Classes 5.1, 5.2, 8



**Hazardous
Non-Compatibles
Oxidizers
Corrosives
Organic Peroxides**

Hazardous w/Sharp
Hazardous & Infectious



**Dual Waste
Container**

NOTE: Non-compatible waste streams cannot be commingled and MUST be placed/packaged in separate containers

Who is Involved

- **Environmental Protection Agency (EPA)**
- **Department of Transportation (DOT)**
- **Drug Enforcement Agency (DEA)**
- **Occupational Safety & Health (OSHA)**
- **Local & State Regulators**
- **Publicly Owned Treatment Works (POTW)**
- **The Joint Commission (TJC)**

A Common Goal with Different Needs

“One Size Doesn’t Fit All”

Industry Sector	Status	Dispense	Return	Disposal
Hospitals	LQG/SQG	X	X	X
Pharmacies	SQG/CESQG	X	X	X
Clinics/Physicians	SQG/CESQG	X		X
Long-term Care	SQG/CESQG			X
Residential Consumers	Household			X

40 CFR Parts 260 to 265

- Waste Generator Status
- EPA ID number
- HW determination
- HW accumulation area
- Emergency Coordinator (**LQG**)
- Emergency Contingency Plan
- Satellite accumulation
- Training
- DOT Regulations
- Manifest Haz Shipment
- Documentation/reporting
- HW transport & disposal

Large Quantity Generator (40 CFR Part 262)

- > = 1000 kg/mo of non-acute hazardous waste
- > = 1 kg/mo acute hazardous waste (P-Listed)
- > = 100 kg/mo of residue or contaminated soil, waste or other debris from spill clean-up of acutely hazardous waste

Small Quantity Generator (40 CFR Part 262)

- Between 100 kg and 1000 kg/mo of non-acute hazardous waste
- < 1 kg/mo of acute hazardous waste (P-Listed)
- < 100 kg/mo of residue or contaminated soil, waste or other debris from spill clean-up of acute hazardous waste

CESQG Conditionally Exempt Small Quantity Generator (40 CFR 261.5)

- < or = 100 kg/mo of non-acute hazardous waste
- < 1 kg/mo of acute hazardous waste (P-Listed)
- < 100 kg/mo of residue or contaminated soil, waste or other debris from spill clean-up of acute hazardous waste

EPA Regulations: Defining Hazardous Waste

Hazardous Waste Determination (40 CFR 262.11)

- Characteristic Hazardous Waste (40 CFR part 261, Subpart C)
Reactive, Toxic, Ignitable, Corrosive
- Commercial Chemical/Listed Hazardous (40 CFR part 261, Subpart D)

Hazardous Waste Criteria (40 CFR 261.3)

- Hazardous waste criteria (40 CFR 261 Subparts C & D) applies to active and inactive ingredients.
- MSDS information does not generally include information on inactive and inert ingredients.

Incompatible Waste

- Special requirements for incompatible wastes (40 CFR 265.177)
- General requirements for ignitable, reactive, or incompatible wastes (40 CFR 265.17)

DOT regulations - basic requirements (49 CFR):

1. Classification, description, and packaging (173.22)
2. Proper marking and labeling (172.300)
3. Segregation into proper streams (173.21)
4. Training (172.202 & 172.204)
5. **Security (172.800)**

Hazmat Implementation Act:

- Fine section rewritten to raise fines.
- Currently fines average \$30,000 per violation and range up to \$100,000.

U.S. DOT HM229

- If a generator ships hazmat without proper documentation *the carrier must report it or the carrier can be prosecuted with the shipper.*

Incompatible Waste

- Special requirements for incompatible wastes (40 CFR 265.177)
- General requirements for ignitable, reactive, or incompatible wastes (40 CFR 265.17)

Hazardous Waste Segregation (49 CFR Part 173, Subpart D – Definitions, Classification, Packing Group Assignments and Exceptions for Hazardous Material Other Than Class 1 and Class 7)

- Flammable gas, non-flammable gas – Class 2, Division 2.1, 2.2, 2.3 (49 CFR 173.115)
- Flammable liquid – Class 3 (49 CFR 173.120)
- Flammable solid – Class 4, Division 4.1, 4.2, 4.3 (49 CFR 173.124)
- **Oxidizers** – Class 5, Division 5.1 (49 CFR 173.127)
- **Organic Peroxide** – Class 5, Division 5.2 (49 CFR 173.128)
- **Corrosives** – Class 8 (49 CFR 173.136)
- Toxic or poisonous material – Class 6, Division 6.1 (49 CFR 173.129)



A Regulatory and Permit Issue

DOT Regulations

- Hazardous Waste Segregation (49 CFR Part 173, Subpart D)

EPA Regulations

- Special requirements for incompatible wastes (40 CFR 265.177)
- General requirements for ignitable, reactive, or incompatible wastes (40 CFR 265.17)

EPA Permit Issues

- EPA permits are issued to facilities which transport, transfer and treat waste
- Not all facilities are permitted to take all types of wastes
- Check with your transporter and hazardous waste facility

EPA - RCRA Training (40 CFR §265.16)

- Employees involved with or occupationally exposed to hazardous waste
- Initial training within 6 months & annual retraining

DOT Training (49 CFR §172.702 & §172.704)

- Employees involved with or occupationally exposed to hazardous materials
- Must be completed within 90 days with retraining every three years

OSHA Hazard Communication Training (29 CFR §1910.1200)

- Employees involved with or occupationally exposed to hazardous chemicals
- Upon initial assignment to the job or whenever a new chemical has been introduced into the employee's area that could present a potential hazard.

OSHA 24 Hour Training 1910.120(e)(3)(iii)

EPA Interpretations & Guidance Statements

Epinephrine Exclusion

- Allows disposal of used epinephrine syringes in red sharps containers as regulated medical waste

Medicinal Nitroglycerin

- Recognizes medicinal levels of nitroglycerin as non-reactive
NOTE: Does not address characteristic of ignitability of preservative in injectable forms of nitroglycerin

Epinephrine Salts

- Epinephrine salts/hydrochloride (P042) deemed non-hazardous

Exceptions for Transportation of Small Aerosols

- Small containers (50ML or less) of Non-flammable aerosols deemed non-hazardous
NOTE: Does not apply to flammable aerosols

SHIPPING UNIVERSAL WASTE

If shipping universal waste to another Michigan universal waste handler or destination facility:

- **“US DOT hazardous materials must be packaged**, labeled, marked, placarded and shipping papers prepared according to US DOT regulations prior to shipment off-site, in addition to universal waste requirements.”

If shipping to another state’s universal waste handler or destination facility:

- “If the universal waste is being shipped to or through a state that does not recognize the waste as universal waste, **a waste manifest must be prepared** according to the receiving state’s requirements.”

STORAGE, HANDLING AND DISPOSAL

- **Keep incompatible pharmaceuticals segregated** and adequate distance apart to prevent them from reacting with each other.

UNIVERSAL WASTE TRANSPORTER REQUIREMENTS

- Required to **comply with all applicable US DOT regulations**, including having the shipment **properly packaged**, labeled, marked, placarded, and transported with the proper shipping papers {40 CFR 273.52}.
- Not required to use a waste manifest, unless the waste is being transported in a State that does not recognize it as a universal waste. If a waste manifest is used, then the transporter must meet all that State’s applicable manifest requirements.



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PROGRAM IMPLEMENTATION AND SORTING OPTIONS

Hospital wide assessment

Objectives:

- Identify current Rx waste disposal practices
- Identify Satellite Accumulation Areas for container placement & needs
- Evaluate current hazardous waste storage practices/storage area
- Identify potential program implementation issues
- Determine specific treatment area requirements
- Identify employee training needs



Waste Characterization

- Identify hazardous waste per EPA RCRA regulations:
 - Listed (Commercial Chemical)
 - Characteristic
- Identify hazardous waste based on **BOTH** active and inactive/preservative ingredients
- MSDS' do not include inactive/preservative ingredient information
- Identify at NDC level (especially injectables)
- Identify DOT hazardous waste classes



EPA Requirements for Satellite Accumulation areas:

- At or near point of generation
- Under generator's control
- Up to 55 gal haz waste or 1 quart of P Listed waste
- When volume threshold is met, transfer container to a hazardous waste storage area within 72 hours



Waste Sorting Options for Satellite Accumulation Areas

1. Compatible (including hazardous and non-hazardous wastes) vs. Non-compatible hazardous wastes
2. Full Hazardous waste sort and separate non-hazardous wastes
3. DOT Level – full hazardous waste with all hazard classes separated out
4. All in one container



Hazardous Waste Storage

- When removed from a satellite accumulation area, satellite containers must be placed in a designated hazardous waste storage area pending manifested shipment.
- “Satellite to satellite” transfer not covered in EPA regulations
- Manifested waste pick-up within 90 (LQG) or 180 days (SQG) longer period allowed for CESQG
- Specific EPA requirements for hazardous waste storage areas



Waste Transport & Disposal

- Waste Stream Profiles
- Due diligence of hazardous waste transport & disposal facilities to ensure proper permitting
- Audit reports & current insurance certificates
- DOT manifests and Certificates of Destruction and land disposal restrictions (LDR)
- DOT disposal containers with compliant labeling
- Appropriately scheduled waste pick-ups



Regulatory Summary

- Pharmaceuticals are included in EPA/RCRA(Resource Conservation and Recovery Act) hazardous waste regulations of 1976.
- EPA, DOT & MIDEQ regulatory oversight.
- Increased EPA Regulatory Activity and enforcement activities at hospital level.
- EPA fines \$41K-\$275K, DOT fines \$30K-\$100K
- EPA-reverse distribution systems cannot be used as a waste management service
- Pharmaceutical waste is a regulatory reality
- Complicated issue and many questions still remain



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RX Waste Compliance

Thank You
Questions & Answers